CAPILLARY FLOW SOLID PHASE ASSAY

CLAIM OF PRIORITY

This application claims priority under 35 USC §119(e) to U.S. Patent Application Ser. No. 61/203,924, filed on Dec. 31, 2008, the entire contents of which are hereby incorporated by reference.

BACKGROUND

This application relates to capillary flow assays.

Various lateral flow assay techniques can be used to determine the presence or absence of analytes in a sample. For example, lateral flow assay can be used to detect the presence of drugs in bodily fluids such as blood, urine, saliva and other liquid samples. A lateral flow assay device includes a single continuous solid piece of absorbent material that allows analytes to move from one end of the material to the other end once a sample containing the analytes is in contact with the one end of the material.

SUMMARY

Techniques, systems and apparatus are disclosed for implementing a capillary flow assay device that can detect a presence of target analytes in a sample. Additionally, a collection unit can be implemented with the capillary flow assay device to collect and retain the sample to confirm the assay findings.

In one aspect, a system for performing lateral capillary flow assay includes a sample collection unit to collect a sample liquid; and a sample testing and storing unit to interface with the sample collection unit to test and store the collected sample liquid. The sample testing and storing unit includes a sample inlet shaped to receive the collected sample from the sample collection unit. The sample testing and storing unit includes a sample well positioned below the sample inlet to retain at least a portion of the sample liquid. The sample testing and storing unit includes a sample housing unit to store a remainder of the sample liquid not retained in the sample well. The sample testing and storing unit includes an analyte testing unit housing shaped to receive an analyte testing unit to test a presence of a target analyte in the sample liquid. The analyte testing unit includes a sample receiving area to receive the sample liquid. The analyte testing unit includes an indicator holding area to temporarily hold at least one type of indicator material that binds with a corresponding target analyte in the sample liquid to form an analyte-indicator complex that flows across the analyte testing unit under capillary action. The analyte testing unit includes at least one binding area to immobilize at least one type of binder material configured to bind with the at least one type of indicator material, at least one analyte, or both the at least one analyte and the at least one type of indicator material. A presence of the corresponding type of indicator material at the at least one binding area indicates an absence of a corresponding type of target analyte. The analyte testing unit includes a validation area that includes a ligand or a binder material that selectively binds to the at least one type of indicator material to confirm that the at least one type of indicator material properly flowed across the analyte testing unit under capillary action.

Implementations can optionally include one or more of the following features. The analyte testing unit can include a single test strip with at least a portion of the single test strip that includes the sample receiving area positioned within the sample well to receive the sample liquid in the sample well. The analyte testing unit housing can include an analyte testing unit inlet positioned above the sample well to allow the single test strip to drop towards the sample well by gravity and in physical contact with the sample liquid in the sample well. The analyte testing unit can include the sample receiving area and the indicator holding area, and at least one binding area and the validation area. an absorbent material positioned at the end of the strip to hold the liquid that has flew through the binding areas and validation area on the membrane.

The analyte testing unit can include multiple structures that includes a first structure that includes the sample receiving area and the indicator holding area, and a second structure that is physically separated from the first structure. The second structure can include the at least one binding area and the validation area. The second structure can include an absorbent material positioned at the end of the strip to hold the liquid that has flew through the binding areas and validation area on the membrane The analyte testing unit housing can include an analyte testing unit inlet positioned above the sample well to allow the second structure of the analyte testing unit to drop towards the sample well by gravity and in physical contact with the first structure of the analyte testing unit. The indicator material can include a ligand and a label that can be visualized based on color or measured for fluorescent, magnetic, chemiluminescent and colormetric signals. The label can include an agent selected from a group comprising a gold colloid, latex nanoparticles, iron nanoparticles, an enzyme, a fluorescent material, and a chemiluminescent material. The label can be directly or indirectly linked to the ligand. The ligand can include a chemical substance that selectively binds with the at least one analyte, the binder material or both the at least one analyte and the binder material. The at least one analyte can include a chemical substance that selectively binds with the ligand, the binder material or both the ligand and the binder material. The binder material can include a chemical substance that selectively binds with the ligand, the indicator material or both the ligand and the indicator material. A filtering unit can be attached to an inner surface of the sample inlet to filter the sample liquid received from the sample collection unit.

In another aspect, a device for assaying a sample can include an analyte testing unit to test a presence of a target analyte in a sample liquid. The testing unit includes a sample receiving structure. The sample receiving structure includes a sample receiving area that includes an absorbent material to receive the sample liquid; and an indicator holding area to temporarily hold at least one type of indicator material that binds with a corresponding target analyte in the sample liquid to form an analyte-indicator complex that flows across the analyte testing unit under capillary action. The testing unit includes a sample testing structure. The sample testing structure includes at least one binding area to immobilize at least one type of binder material configured to bind with the at least one type of indicator material, at least one analyte, or both the at least one analyte and the at least one type of indicator material. A presence of the corresponding type of indicator material at the at least one binding area indicates an absence of a corresponding type of target analyte. The sample testing structure includes a validation area comprising a ligand or a binder material that selectively binds to the at least one type of indicator material to confirm that the at least one type of indicator material properly flowed across the analyte testing unit under capillary action.

Implementations can optionally include one or more following features. The sample receiving structure can include a first test strip; and the sample testing structure can include a second test strip physically separate from the first test strip. In some implementations, the analyte testing unit can include a